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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/492,028 01/26/00 ZUKER

C 02307E-09261

020350 HM12/1107
TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO CA 94111-3834

EXAMINER

O'LAUGHLIN, R

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

11/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/492,028

Applicant(s)

ZUKER, CHARLES S.

Examiner

Bridget E. O'Laughlin-Bunner

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8, drawn to a method for identifying a compound that modulates sensory signaling in sensory cells comprising contacting the compound with a sensory cell specific G-protein alpha subunit polypeptide and determining a functional effect of the compound upon the polypeptide by binding radiolabeled GTP, classified in class 424, subclass 1.69.
 - II. Claims 1, 4-5 and 9-22, drawn to a method for identifying a compound that modulates sensory signaling in sensory cells comprising expressing a G-protein alpha subunit polypeptide in a cell, expressing a G-protein coupled receptor in the cell, and determining the functional effects of a compound upon the polypeptide, classified in class 435, subclass 4.
 - III. Claims 23-24, drawn to a method for identifying a compound that modulates sensory signaling in sensory cells comprising expressing a sensory cell specific G-protein alpha subunit in an HEK 293 cell, expressing a G-protein coupled receptor in the cell, contacting the cell with a modulating compound, and determining changes in intracellular calcium levels, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Inventions I, II and III are different methods because they require different ingredients, process steps, and endpoints. These inventions require different ingredients and process steps to identify a compound that modulates sensory signaling. Groups I, II and III are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention I requires search and consideration of contact of a compound with a G-protein alpha subunit polypeptide, binding radiolabeled GTP to the polypeptide and measurement of radiolabeled GTP, which is not required by the other inventions. Invention II requires search and consideration of coexpression of a G-protein alpha subunit polypeptide and a sensory cell specific G-protein coupled receptor in a cell and measurement of electrical activity, phosphorylation, transcription levels, and cAMP or cGMP levels, which is not required by the other inventions. Invention III requires search and consideration of coexpression of a G-protein alpha subunit polypeptide and a sensory cell specific G-protein coupled receptor in a cell and measurement of intracellular calcium levels.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for identifying a compound that modulates sensory signaling comprising contacting a compound with a sensory cell specific G-protein and determining a functional effect of the compound upon the polypeptide, wherein the functional effect is:

Ia. a chemical effect

Ib. a physical effect

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2-3, 6-24 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for identifying a compound that modulates sensory signaling comprising coexpressing a G-protein alpha subunit polypeptide and a G-protein coupled receptor, contacting the cell with a compound and determining a functional effect of the compound upon the polypeptide, wherein the functional effect is measured by:

- Ic. changes in the electrical activity of cells expressing the G-protein alpha subunit polypeptide
- Id. changes in the level of phosphorylation of sensory cell specific proteins
- Ie. changes in transcription levels of sensory specific genes
- If. changes in intracellular cAMP, cGMP, IP₃, DAG, or Ca²⁺

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 2-5, 7-8, 11, 15-24 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

If applicant selects Invention I or II, one species from the type of functional effect group must be chosen to be fully responsive.

If applicant selects Invention II, one species from the measurement of functional effect group must be chosen to be fully responsive.

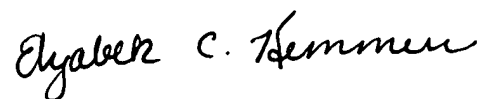
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. O'Laughlin-Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bridget O'Laughlin-Bunner
Art Unit 1647
November 3, 2000



ELIZABETH KEMMER
PRIMARY EXAMINER